

REMARKS

Claims 1 – 14 remain in this application. Claims 1 – 14 have been amended. Reconsideration of this application in view of the amendments noted is respectfully requested.

With respect to claim amendments, claim 1 has been amended to define that the “stress state” is “associated with body balance wherein the overall cardiovascular function is substantially higher than immediate physical metabolic requirements.” Support for this definition can be found on page 2, lines 20 – 24 of the specification. Applicant has also amended claim 1 to move “wherein ambulatory heart beat signal is measured” from the preamble. Further, applicant has amended claim 1 to improve the syntax of the claim.

Applicant has also amended claims 2 – 14 to improve the syntax of the claims and to correct grammatical errors.

Claims 3, 9, and 10 were rejected under 35 U.S.C. Section 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it was found that there was insufficient antecedent basis for the limitations “the second chosen rule,” “the relaxation index,” and “the total resources index” in claims 3, 9, and 10, respectively.

With respect to rejection of claim 3, applicant has amended “a predetermined rule” in the last paragraph of claim 1 to read --a predetermined second chosen rule--. Hence, there is now sufficient antecedent basis for “the second chosen rule” in claim 3, which depends directly from claim 1. In relation to this amendment, for consistency applicant has amended the term “a chosen rule” appearing earlier in claim 1 to now read --a first chosen rule--. This is also consistent with claim 2 (depending from claim 1), which recites “the first chosen rule.”

With respect to claim 9, applicant has amended “the relaxation index” to read --a relaxation index--. Similarly, in claim 10, applicant has amended “the total resources index” to read --a total resources index--.

Applicant submits that the claims are now definite and respectfully requests that the Section 112, second paragraph rejection of claims 3, 9, and 10 be withdrawn.

The abstract was objected to because the language “the invention” should be deleted. Applicant has amended the abstract accordingly.

The specification was objected to because on page 8, line 12, “generalized likelihood ratio” should be --generalized likelihood ratio (GLR)--. Applicant has amended the specification accordingly.

Claims 1 – 7 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Swanson et al. (U.S. Patent No. 5,788,645, hereinafter “Swanson”). Applicant respectfully traverses this rejection.

Swanson discloses a method to evaluate cardiac rhythm in connection with implantable cardiac treatment systems. Different cardiac rhythms can be classified as normal sinus rhythm, sinus tachycardia, ventricular tachycardia, and supraventricular tachycardia. Several measures of cardiac function are determined: atrial rate, ventricular rate (RR-intervals) and atrial to ventricular intervals. In the measurement of these parameters, a plurality of cardiac sensing electrodes are necessary. Specifically, these sensing electrodes may provide one or more features extracted from the following signals during each cardiac event: ventricular flow, ventricular pressure, ventricular volume, cardiac electrogram, cardiac electrogram gradient, or arterial blood flow.

The arrhythmia classification method disclosed in Swanson includes a separate exponential event filter that is an adaptable filter for determination of cardiac arrhythmias. The exponential event filter takes into account the effect of physical exercise on ECG waveform morphology when classifying the arrhythmias, thus not classify small exercise induced changes in ECG waveform morphology as ventricular tachycardia but instead as sinus- or supraventricular tachycardia.

Swanson, however, fails to disclose a method wherein data segments with elevated cardiac activity due to increased metabolic rate are excluded from an ambulatory heart beat signal wherein the remaining segments are potential stress state, as in the present invention.

Further, the method of Swanson is not related to assessment of stress (as in the present invention) but rather to evaluation of cardiac rhythm, specifically whether a normal sinus rhythm or one of the above mentioned tachycardias is prevailing.

For these reasons, claim 1 is patentable over Swanson. Claims 2 – 7, depending from claim 1, are therefore also patentable over Swanson. Hence, applicant respectfully requests that the Section 102(b) rejection of claims 1 – 7 as being anticipated by Swanson be withdrawn.

Claims 1 – 7 and 11 – 14 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Arnold et al. (U.S. Patent No. 5,713,367, hereinafter “Arnold”). Applicant respectfully traverses this rejection.

Arnold discloses a method of measuring and assessing cardiac electrical stability with a special reference in assessment of (T-wave) alternans in an ECG signal. The basis of the method of Arnold is the measurement and analysis of ECG-signal waveforms rather than RR-interval durations of ECG signals as in the present invention. Arnold induces a heightened heart rate (and refers to it as “stress”) by means of exercise or pharmacological agents, and then those segments with increased heart rate are detected. Arnold is not concerned with the reasons why the heart rate is increased, and the alternans are detected from all segments with high heart rate without detecting the reason for the increased heart rate.

Further, in Arnold, segments are defined from the data but for a different purpose than in the present invention. More specifically, in Arnold abnormal beats in a beat sequence are identified and removed or replaced and the level of alternans is determined using the beat sequence free of abnormal beats. These removed/replaced abnormal beats, however, are not caused by elevated cardiac activity but instead are caused by measurement error or cardiac electrical instability. Arnold also discloses that noise in ECG-signals caused by possible exercise activity is taken into account when an ECG is analyzed. However, Arnold does not exclude data segments with exercise activity (elevated cardiac activity) from the data. In contrast, in the method of the present invention, segments are

defined from a heart beat signal, and all data segments with elevated cardiac activity are excluded from the beat sequence wherein the remaining data is potential stress state. Arnold does not disclose this feature of the present invention.

Moreover, Arnold is not related to the assessment of stress but rather to the assessment of a patient's cardiac electrical stability.

For all of these reasons, Arnold does not teach the present invention as claimed in claim 1. Hence, applicant submits that claim 1 is patentable over Arnold. Claims 2 - 7 and 11 - 14, depending from claim 1, are therefore also patentable over Arnold. Hence, applicant respectfully requests that the Section 102(b) rejection of claims 1 - 7 and 11 - 14 as being anticipated by Arnold be withdrawn.

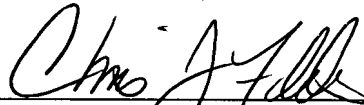
Claims 8 - 10 were objected to as being dependent upon a rejected base claim, but were found allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This amendment and request for reconsideration is felt to be fully responsive to the comments and suggestions of the examiner and to place this application in condition for allowance. Favorable action is requested.

Respectfully submitted,

Joni Kettunen et al.

Fildes & Outland, P.C.

A handwritten signature in black ink, appearing to read "Chris J. Fildes", is written over a horizontal line.

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